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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,216	04/07/2004	Reinhardt B. Baudy	AM101277(WYNC-2142)	7281

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EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	**PAPER NUMBER**
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/820,216	**Applicant(s)** BAUDY ET AL.	
	Examiner Brenda L. Coleman	**Art Unit** 1624	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): see attached.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *1-8,10 and 29*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *9 and 11-28*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: 892

Brenda Coleman

Brenda L. Coleman
Primary Examiner
Art Unit: 1624

ADVISORY ACTION

The period for reply continues to run THREE MONTHS from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 or a request for a continued examination (RCE) in compliance with 37 CFR 1.114 must be timely filed to avoid abandonment of this application.

The amendment filed February 20, 2007 under 37 CFR 1.116 in reply to the final rejection has been entered, but is not deemed to place the application in condition for allowance. For purposes of appeal, the status of the claims is as follows:

Allowed claim(s): 1-8, 10 and 29

Rejected claim(s): 9 and 11-28

Claim(s) objected to: NONE

This action is in response to applicant's amendment dated February 20, 2007.

Response to Arguments

Applicant's amendments filed February 20, 2007 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 11-28 labeled paragraph 1 maintained in the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. The applicants' stated

that, with respect to the prevention of disorders, no evidence has been presented that there is any reason to believe that a skilled artisan would doubt that the compounds of the invention would not be useful in preventing opiate tolerance, especially in light of the fact that NMDA receptor antagonists are known to prevent the opiate analgesia tolerance. See, for example, the Trujillo abstract (previously provided). Contrary to the allegations in the latest action, this abstract indicates that a decade of research establishes that "NMDA receptor antagonists have the ability to inhibit opiate tolerance," even if the exact mode of action is not known. Furthermore, medical professionals have means to measure tolerance to opiate analgesia and would have no difficulty administering the compounds of the invention to affect the desired result, i.e., prevention of the tolerance. No other evidence has been presented that establishes that a skilled artisan would doubt the use of the compounds of the invention, which are NMDA receptor antagonists, would not be useful in the treatment of the listed diseases and conditions.

As stated in the last office action where structure sensitivity exists (in the pharmaceutical art) degree of testing must be representative of claims' scope. Note In re Fisher 166 USPQ 18; In re Surrey 151 USPQ 724. The recent journal article, i.e. Lipton (2004), herein provided indicates that many NMDA receptor antagonists have disappointingly failed advanced clinical trials for a number of diseases including stroke and neurodegenerative disorders such as Huntington's disease. Thus the uses being urged are not in currently available form based on the activity relied on and the

specification provides only a starting point for further research. Note Genentech vs. Novo Nordisk 42 USPQ 2d 1001.

Claims 11-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. With regards to the 35 U.S.C. § 112, second paragraph rejection labeled 2) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicant's stated that with respect to the phrase "pain relieving agent" a skilled artisan would have no difficulty understanding the meaning of the phrase. The phrase "pain relieving agent" is a relative term, which unduly functional and renders the claim indefinite. The term "pain relieving agent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprized of the scope of the invention. Names, structures, and chemical Formulae precisely define organic molecules. Attempting to define structure by function is not proper when the structures can be clearly expressed in terms that are more precise. Additionally, it is not sufficient to define a chemical structure solely by its principal biological property. The nature of the complex compositions, which consists of a compound of formula I and an additional active ingredient (a pain relieving agent) is vague and indefinite, for reasons of record and stated above.

Claims 23 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

3. With regards to the provisional obviousness-type double patenting rejection as being unpatentable over copending Application No. 10/820,215 of the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 11-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-55 of copending Application No. 10/820,215, for reasons of record.

4. With regards to the provisional obviousness-type double patenting rejection as being unpatentable over copending Application No. 10/961,871 of the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 11-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-95 and 104-108 of copending Application No. 10/961,871, for reasons of record.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 5a), b), d), f), g) and h) of the last office action, which are hereby **withdrawn**. However with regards to the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 5c) and e) the applicant's amendments and remarks have been fully considered but they are not persuasive.

c) The applicant's stated that the species e) has been amended to correct the typographical error with respect to the extraneous hyphen in the name of the compound. However, this is not so. The nomenclature of the species is such that there is a hyphen still present, i.e. phospha**hep-t**-1-yl in the species labeled e).

Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

e) The applicant's stated that the species e) has been amended to correct the typographical error with respect to the extraneous hyphen in the name of the compound. However, this is not so. The nomenclature of the species is such that there is a hyphen still present, i.e. phospha**hep-t**-1-yl in the species labeled e).

Claim 28 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

Allowable Subject Matter

Claims 1-8, 10 and 29 are allowed. None of the prior art of record or a search in the pertinent art area teaches the compounds of formula (I) as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brenda Coleman

Brenda L. Coleman
Primary Examiner Art Unit 1624
March 7, 2007